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Brevet canadien / Canadian Patent

♦ Le commissaire aux brevets a reçu une demande de délivrance de brevet visant une invention. Ladite requête satisfait aux exigences de la *Loi sur les brevets*. Le titre et la description de l'invention figurent dans le mémoire descriptif, dont une copie fait partie intégrante du présent document.

Le présent brevet confère à son titulaire et à ses représentants légaux, pour une période expirant vingt ans à compter de la date du dépôt de la demande au Canada, le droit, la faculté et le privilège exclusif de fabriquer, construire, exploiter et vendre à d'autres, pour qu'ils l'exploitent, l'objet de l'invention, sauf jugement en l'espèce rendu par un tribunal compétent, et sous réserve du paiement des taxes périodiques.

♦ The Commissioner of Patents has received a petition for the grant of a patent for an invention. The requirements of the *Patent Act* have been complied with. The title and a description of the invention are contained in the specification, a copy of which forms an integral part of this document.

The present patent grants to its owner and to the legal representatives of its owner, for a term which expires twenty years from the filing date of the application in Canada, the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication before any court of competent jurisdiction, and subject to the payment of maintenance fees.

BREVET CANADIEN	**2114848**	CANADIAN PATENT
Date à laquelle le brevet a été accordé et délivré	**1996/04/23**	Date on which the patent was granted and issued
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Commissaire aux brevets/Commissioner of Patents

Canada

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(54) Medical Connector

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MEDICAL CONNECTOR

Background of the Invention

Field of the Invention

This invention relates to medical connectors used in the treatment of the injured or sick, and in particular to a connector for introducing medication into a patient in a safe, convenient way.

Background Discussion

It is a common practice in treating patients, particularly patients who must be cared for under emergency conditions, with medication introduced into the patient intravenously. An intravenous solution, commonly referred to as parenteral liquid, is fed from a container holding this liquid. The liquid flows through tubing into a needle which has been inserted into the patient's vein. The needle is taped securely to the patient's body and is not likely to pull loose if the patient moves. Medication needed to sustain the life of the patient, for example, drugs which maintain the blood pressure of the patient at the desired level, are added to the parenteral liquid. The conventional practice is to introduce the medication through a second needle inserted into a sealed entry port in the tubing through which the parenteral liquid flows.

One problem with this conventional practice is that the needle may be pulled loose from the sealed port relatively easily. Such accidental removal of the needle from the sealed port can have very serious consequences and could even lead to the death of the patient. Although many hospitals require nurses to tape the needle securely to the tubing, this is not always done, because taping is a burdensome and time consuming task.

A second problem with the conventional practice is needle sticks. From time to time a nurse in attempting to insert the needle into the sealed entry port will accidentally stick himself or herself with the needle. This often occurs under emergency conditions when the nurse is under pressure to complete this task as quickly as possible. Not only is the

accomplishment of the task delayed but the nurse must stop working and have a blood test performed. Such a test is needed in case the nurse becomes infected, because the hospital will be responsible financially. Consequently, needle sticks not only result in increased hospital cost, but are a possible life threatening event to the nurse.

A third problem with the conventional practice is infection. All too often a patient's life is seriously endangered by bacteria gaining entry into a patient's blood stream and establishing an infection. In a vast number of cases it is unknown how the bacteria gain entry. We have observed conditions in hospitals and identified that one likely way the bacteria gain entry is by contamination of the needle inserted into the sealed entry port. This happens when the nurse notices that the needle has been pulled loose and simply reinserts it even though it may now have on its surface bacteria picked up by direct contact with, for example, the patient's bedding. Another possible way that bacteria may gain entry into the patient's blood stream is through contamination of the tape used to hold the needle to the connector.

Summary of the Invention

The present invention provides a safety connector for connection to the branch port on a fluid flow line having a branch port thereon. The connector comprises a tubular body having an opening at the distal end thereof for receiving the branch port; a channel in the wall of the tubular body, adjacent the distal end thereof, for receiving the fluid flow line when the branch port is engaged within the tubular body; and a locking collar rotatably disposed on the distal end of the tubular body, the collar rotatable from a first position in which the channel is adapted to receive the fluid flow line when the branch port is engaged within the tubular body, and a second position in which the collar prevents removal of the branch port from the tubular body. Preferably, the branch port is on a piggyback connector of the type adapted for combining the fluid flow from two different sources of

parenteral fluids, and the two influent lines and the one effluent line of the piggyback connector are arranged in a substantially Y-shaped configuration. The branch port preferably comprises a generally tubular shaped body having a pierceable septum thereon. In a preferred embodiment, the safety connector also includes a luer connection on the interior of the tubular body at the proximal end thereof for receiving the hub of a hollow needle which, when installed, extends distally within the tubular body. In this preferred embodiment, the distal end of the needle is disposed within the tubular body at a sufficient distance from the distal end thereof so as to substantially prevent contact between the distal end of the needle and the fingers of an operator handling the safety connector.

Another aspect of the present invention provides a method of securing a second influent fluid line to the branch port on a generally Y-shaped piggyback connector, the connector having a first influent fluid line on one side of the Y-shaped connector and a pierceable septum on the other side of the Y-shaped connector. This method comprises the following steps: providing a safety connector of the type having a generally tubular body with a needle therein adapted to engage the pierceable septum on the branch port; advancing the tubular connector in the direction of the branch port so that the needle within the connector pierces the septum on the branch port and the first influent line is received within an axially extending slot in the wall of the connector; and rotating a rotatable collar on the distal end of the connector to form an enclosure around the first influent line, thereby maintaining the second fluid line in fluid communication with the piggyback connector, and substantially preventing the retraction of the port from the tubular body. The rotatable collar is preferably rotatable between a first position in which the axially extending slot is open to the distal end of the wall for receiving the first influent line, and a second position wherein the distal end of the axially extending slot is occluded, thereby preventing the removal of the first

influent line in an axial direction. The rotatable collar preferably provides aural and tactile feedback to the user when the rotatable collar is moved from the first position into the second position.

In yet another aspect of the present invention, a safety connector for placing an influent fluid line in fluid communication with an effluent fluid line is provided. This effluent fluid line has a pierceable septum thereon and a projection extending radially therefrom proximate the pierceable septum. The connector comprises an elongate tubular body having proximal and distal ends thereon; a needle removably disposed in the tubular body, the needle having a proximal attachment end and a sharpened distal end, the proximal end of the needle secured to the proximal end of the tubular body, the needle extending in the distal direction within the tubular body; a slot in the wall of the tubular body extending axially from the distal end in the direction of the proximal end, the slot adapted to receive the projection on the fluid line; and a rotatable collar disposed on the distal end of the tubular body, the collar adapted to rotate between a first position in which the slot is unobstructed so that the projection may be introduced therein when the pierceable septum on the effluent fluid line is engaged by the needle, and a second position in which the distal end of the slot is obstructed to substantially prevent the removal of the projection therefrom, thereby preventing removal of the needle from engagement with the pierceable septum. This safety connector preferably includes a recess on the tubular body for receiving a projection on the collar when the collar is in the second position, thereby producing an audible click when the collar is rotated to dispose the projection within the recess.

The projection preferably comprises an axially oriented ridge which extends radially inwardly from the collar. The safety connector also preferably includes a substantially cylindrical surface on the exterior distal end of the tubular body for slidably receiving the rotatable collar. Preferably, the cylindrical surface comprises at least one annular

shoulder thereon for receiving a radially inwardly extending annular flange on the rotatable collar to rotatably secure the collar to the surface. In one embodiment, the rotatable collar further comprises friction enhancing structures on the exterior surface thereof. Preferably, the rotatable collar is provided with a discontinuity which, when aligned with the slot in the wall of the tubular body, provides an axially extending slot for receiving the projection in an axial direction, wherein rotation of the rotatable collar from the first position into the second position rotates the discontinuity in the collar out of alignment with the slot in the wall of the tubular body, thereby entrapping the projection and preventing axial withdrawal of the effluent fluid line. This embodiment of the invention also preferably includes a male luer connector on the exterior of the proximal end of the tubular body. In a preferred embodiment, the tubular body is further provided with a radially outwardly extending stop which is received in a circumferential channel on the radially inwardly facing surface of the rotatable collar, the circumferential length of the channel providing limits to the range of rotation of the rotatable collar with respect to the tubular body.

Major Features of the Invention

The problems discussed in the BACKGROUND OF THE INVENTION present a serious health hazard to patients and their nurses. The present invention eliminates these problems and provides a medical connector which is both safe and convenient to use.

There are several features of this invention which contribute to its safety and convenience, no single one of which is solely responsible for these desirable attributes. Many of these features were present in our experimental versions of the invention, which were improved after testing. Without limiting the scope of this invention as expressed by the claims, its more prominent features will now be discussed briefly. After considering this discussion, and particularly after reading the section of this application entitled DETAILED DESCRIPTION OF THE DRAWING, one will understand how

the features of this invention provide the attributes of safety and convenience.

One safety feature of this invention is the use of a cap member to enclose the needle to be inserted into the sealed entry port structure. This cap member fits snugly over the entry port structure, connecting with the port structure in a male-female mating relationship. The needle pierces the seal when the cap member is seated on the port structure. This needle is housed deep within a cavity in the cap member that terminates in an open mouth into which the sealed end of the port structure fits. This open mouth is narrow in width so that the finger of the nurse or patient cannot fit into the cavity and contact the needle. Since the needle is so mounted within the cap member, the likelihood of bacterial contamination is avoided or reduced and the nurse is protected against accidental needle sticks.

A second safety feature is provided by the wall design of the cap member and port structure. These walls are of preferably cylindrical configuration and engage each other like a telescope. The interior surface of the wall of the cap member slides over the exterior surface of the wall of the mating port structure, with these walls engaging each other to guide the needle into the center of the seal. This ensures that the needle does not scrape against the inside surface of the wall of the port structure. Particles scraped from this wall could make their way into the patient's blood stream and result in death. This potentially lethal condition is inherent in the design of conventional devices. But the connector of this invention, with the guideway wall design of the cap member and port structure, ensures that the needle is directed into the center of the seal so that it avoids scraping against the inside surface of the wall of the port structure. This guideway wall design also permits the nurse quickly to connect the cap member to the port structure. This makes the connector of this invention not only more convenient to use, but in emergencies, enables the nurse to administer

medication to a patient faster than with conventional devices and doing it without the danger of needle sticks.

A third safety feature of the invention is that a locking mechanism detachably secures the cap member to the port structure. Because of this feature, movement of the patient does not result in accidental removal of the needle from the seal. Although many different types of locking mechanisms may be employed, the preferred one provides a sound upon locking engagement of the cap member and port structure. We have devised such a locking mechanism which produces a sound such as "click." This "click" is an audible signal which tells the nurse that the cap member is locked safely to the port structure and cannot be accidentally jarred loose by movement of the patient.

Certain embodiments of the invention illustrating all the features of this invention will now be discussed in detail. These embodiments show the invention being used for administering medication intravenously to a patient. This invention may also be used to administer medication to a patient in other ways, for example, intracranially or intraperitoneally.

Brief Description of the Drawings

The drawing, wherein the numerals indicate like parts, depicts four embodiments of this invention in which:

Fig. 1 is a schematic view illustrating administering medication intravenously to a patient in accordance with conventional practice.

Fig. 2 is a cross-sectional view of a piggyback connector for introducing parenteral liquid and medication intravenously to the patient shown in Fig. 1.

Fig. 3 is a perspective view of the fifth embodiment of the medical connector of the present invention which employs a twist lock means for securing the cap member to a port structure.

Fig. 3a is a planar view of the distal end of the embodiment shown in Fig. 3 with the locking collar in the open position.

Fig. 3b is a planar view of the distal end of the embodiment shown in Fig. 3 with the locking collar in the closed, locked position.

Fig. 4 is an exploded elevational view of the embodiment shown in Fig. 3.

Fig. 5 is a perspective view of the cap member of the embodiment shown in Fig. 3, with the locking collar in the open position.

Fig. 6 is a perspective view of the cap member of the embodiment shown in Fig. 3, with the locking collar in closed, locked position.

Fig. 7 is a perspective view showing how the cap member prevents needle sticks.

Detailed Description of the Drawing

Conventional Connector System

As shown in Figs. 1 and 2, the current way of intravenously introducing parenteral liquid into a patient is by the conventional feeding system 10. This feeding system 10 includes a container 12 for the parenteral liquid, a tube 14 extending from the container and connected to a Y or "piggyback" connector 16, and a tube 18 from the piggyback connector to a needle (not shown) inserted into a vein of the patient. The needle is taped to the patient so that movement of the patient will not result in the needle being pulled from the patient's vein.

As best illustrated in Fig. 2, medication from the container 20 is introduced through the piggyback connector 16 into the parenteral liquid flowing through the feeding system 10. This piggyback connector 16 consists of two tubular conduits 22 and 24 which merge into a third tubular conduit 26. The tubing 14 from the container 12 of parenteral liquid is inserted into the inlet port 28 of the conduit 22 and secured in position, for example, by an adhesive which bonds the external surface of this tube to the internal wall surface of the conduit. There is a stop 30 which limits the extent to which this tube 14 can be inserted into the conduit. In a similar fashion, the tube 18 is secured to the outlet port 32

of the piggyback connector. This tube 18 is inserted into the outlet port 32 until it abuts a stop 34 in the internal wall of the conduit. This tube 18 is secured by an adhesive to the internal wall of the conduit 26.

The sealed entry port structure of the conventional feeding system 10 is provided by the branch conduit 24 which has a standard latex rubber seal 36 at its inlet port 38 to seal this port. Consequently, bacteria cannot enter the piggyback connector 16 via the inlet port 38 because of the seal 36. This seal 36 is of conventional design and includes coaxial annular aprons 40 and 42 which fit over the conduit wall 24a and grip the external and internal wall surfaces to hold the seal securely to the conduit 24. A suitable seal may be obtained from the West Company of Phoenixville, Pennsylvania.

The medication is introduced into the parenteral liquid flowing through the piggyback connector 16 by a needle 44 which is inserted through the central part of the seal 36 into the branch conduit 24. This needle 44 is connected by a suitable connector 46 to a tube 48 which is connected to the container 20 (Fig. 1) for the medication. As parenteral liquid flows through the piggyback connector 16 into the inlet port 28 and out the outlet port 32, the medication is drawn into this stream of liquid, flowing from the container 20 via the tube 48 and through the open tip or end 44a of the needle 44 into the parenteral liquid.

After studying Figs. 1 and 2, the several problems associated with the conventional practice can now be more fully understood. If the patient moves, for example, rolls or moves his or her arm, the needle 44 may be pulled from the seal 36. If this occurs, the latex seal 36 has sufficient resiliency to close off the hole in the seal produced by the needle 44. The parenteral liquid will continue to flow into the patient's system, but the necessary medication is no longer being introduced into it. The consequences of this condition are very grave and, if this condition is unnoticed by the nurse, it could result in the death of the patient or

serious complications in the patient's treatment. Even if the nurse notices that the needle 44 has been removed from the seal 36 and reinserts it into the seal, it is possible that the needle has been contaminated with bacteria. The use of such a contaminated needle 44 is unacceptable, but nevertheless this sometimes happens. The needle 44 may be taped to the conduit 24, and many hospitals instruct nurses to do this. When this task is done, the needle 44 is secured, but cannot be conveniently removed and then reinserted. And even when taping the needle 44, if this is not done carefully, the needle may still be contaminated by the nurse touching the needle or the tape being contaminated. Also, because the nurse holds the conduit 24 with one hand while inserting the needle 44, the nurse may accidentally stick the needle directly into the hand holding this conduit, or stick the needle through the conduit wall 24a into this hand. These problems associated with the conventional practice are eliminated by the invention disclosed hereinafter.

Embodiment of the Invention

In an embodiment of the invention it is contemplated that a safety connector locking device contain a collar or ring-type rotating lock mechanism to secure the junction between the flexible intravenous drip tubing extending from the intravenous solution container and the Y or piggyback connector. The lock mechanism contemplated in this embodiment of the invention is advantageously inexpensive to manufacture and simple to use. The embodiment prevents needle sticks, protects the junction from contamination by adventitious agents and generates a "click" sound upon lock engagement.

Figs. 3-6 illustrate this preferred safety connector locking device. Fig. 3 illustrates perspective view in elevation of a preferred embodiment of the safety connector locking device 200. The locking device 200 is designed to fit over a Y or piggyback connector, such as the piggyback connector 16 diagrammed in association with Fig. 2, except that the needle 44, connector 46, tube 48 and outlet port 32, are vertically oriented, and the inlet port 28 extends

radially outward from the side of connector 16. The safety locking device comprises a tubular body or cap member 202, an intravenous drip attachment tube 216 and a rotatable locking collar 212. The cap member 202 forms a hollow tubular chamber 218 that contains a needle 210 in open communication with a second chamber 214 to provide an open channel with the intravenous drip attachment tube 216. Fluid passes from the effluent intravenous drip tube 216 into chamber 214, through needle 210, and during engagement, into an influent port of the Y connector (not shown).

The terms "lower" and "distal" are used in association with this embodiment to describe that portion of a given element of the invention that is in spatial proximity to the Y connector during use. The terms "upper" and "proximal" are spatially defined as that portion of a given element of the invention that is more proximate to the medication container during use. Thus intravenous IV drip attachment tube 216 is connected to the upper rim 224 of cap member 202 and is situated at the proximal end of the apparatus. In this embodiment piggyback connector locking device 212 is associated with the lower rim 230 or distal portion of cap member 202.

The cap member 202 is telescopically tapered with the widest portion of the locking collar 212 at the distal end of the device and narrowing toward the intravenous drip attachment tube 216 at the proximal end. The tapered cap member 202 serves to guide the piggyback connector conduit 22 (see Fig. 2) or branch port of the Y connector into the tubular chamber 218 so that the needle 210 pierces the septum or seal 36 on the conduit to actively engage the entry port of conduit 22 with the needle attachment region. Thus, the junction between the conduit and the safety connector device 200 is protected by the cap member 202 from exposure to adventitious agents.

The needle 210 is suspended from the needle attachment cap 220 such that the needle is centrally located with the tubular chamber. The overall length of the tubular chamber is

such that the needle is recessed into the chamber. The widest portion of the cap member 202 is preferably narrow enough in cross sectional diameter and the needle 202 is recessed sufficiently such that the little finger of a typical adult user cannot enter the tubular chamber and contact the suspended needle as shown in Fig. 7. Preferably the widest portion at the opening, of the tubular chamber 218 is no greater than about one centimeter and the minimum distance between the opening and the needle tip 210a is at least about one centimeter. However, varying conduit or branch port diameters of the Y connector with which the apparatus is used may necessitate slight changes in the diameter of the apparatus 200.

Beginning at the tubular intravenous drip IV attachment tube 216, there are two attachment barbs 222 that extend outwardly from the drip attachment tube. These barbs 222 provide attachment holds for the flexible intravenous drip tubing that extends from the medication container and ends at the safety connector locking device (see Fig.1). Preferably the barbs 222 form a male luer connector for attachment onto intravenous tubing, however other attachment means are contemplated. These would be well known to those individuals with skill in the art, thus no additional discussion is required. It is further contemplated that an adhesive could be used to strengthen the attachment between the flexible intravenous drip tubing and attachment tube 216. The second open chamber 214 permits the continuous flow of liquid from the medication chamber through the safety connector and into the Y connector. Dashed line 215 indicates the continuous opening provided from tubular chamber 214 through the distal region of the cap member 202.

Intravenous drip attachment tube 216 enters through the upper rim of the cap member into tubular chamber 218. The attachment tube 216 telescopically narrows within the tubular chamber toward needle 210 to form a needle attachment site. Needle attachment cap 220 is connected to needle 210 at its proximal end. The needle attachment site is an extension of

the intravenous drip attachment tube that extends into tubular chamber 218. Needle attachment cap 220 preferably connects to attachment tube 216 by a luer-lock fitting. Threads 226 within the tubular chamber facilitate the fitting between the cap member 202 and needle 210. It is additionally contemplated that an adhesive could be used to strengthen the fitting between the needle attachment cap and the distal portion of the attachment tube. Other attachment mechanisms are contemplated and the preferred examples described herein are in no way intended to limit the scope of this embodiment.

Along the length of the cap member and extending toward the distal rim 230 is cap member archway 204. The archway comprises a cut out section along the lower wall of the cap member casing to provide a channel or slot for one arm of the Y connector. Piggyback connectors often are formed in the shape of a Y. These connectors have a straight tubular portion and a lateral arm extending outward. The Y has two arms or branches joining at a crook to form a "V". Each branch forms an influent fluid conduit that is sealed by a pierceable septum. A stalk extending from the crook joins both conduits into a single influent fluid line. During use, one arm of the Y is inserted into the cap member of the disclosed invention. Archway 204 forms a channel or slot for the adjacent arm. The archway fits into the crook to create a snug fit such that the proximal portion of the archway sits within the crook formed by the two branches of the Y. This permits the distal end of the safety connector to extend around the adjacent arm and extend down the stalk of the connector.

With the archway facing the crook of the Y connector, it is possible to lock the safety connector 200 in place following needle engagement. Included in this embodiment of the disclosed invention is a rotatable locking collar 212 that forms a twistable annular collar that glides about the lower rim of the cap member.

Fig. 4 is an exploded elevational view of Fig. 3. Cap member 202 is separated from the rotatable locking collar 212.

In a preferred embodiment, the cap member 202 has a shoulder extension 232 that further broadens the telescopic expansion of the cap member. The width of the lower edge 234 of the shoulder 232 defines the final external width of the safety connector device. Preferably, the distance along the cap member between the lower edge of the shoulder and the distal rim of the cap member 230 defines the height of the rotatable locking collar 212.

With the exception of two cut out regions, the collar locking device comprises an essentially circular ring that is preferably manufactured from the same material as the cap member. The first cut out region of the locking collar, defined as the area between edges 236 and 240, is preferably equal in width to the cap member archway 204 such that in the open or first position (see Fig. 5), the collar and archway are superimposed. The rotatable locking collar is sized just larger than the distal portion of the cap member to permit rotation about a common axis. The collar locking device has a second cut out notch 242 that will be discussed in further detail below.

The distal rim 230 of the cap member has an annular shoulder or slight lip extension 244 that serves as a distal rotation guide for the collar locking device. In addition a second rotational guide 246 is preferably formed as a groove immediately below the lower edge 234 of the cap member shoulder 232. A locking bar 248 is provided along one edge of the archway opening on the cap member and a complementary locking bar 250 is additionally positioned along edge 236 of the collar locking device 212.

Thus, the collar locking device is designed to fit beneath cap member shoulder edge 234 along the rotational guides such that it can rotate around the distal region of the cap member. Annular flange 243 extends radially inward from the collar locking device and follows the cap member lip extension guide 244. As best seen in Figs. 3a and 3b, and also in Figs. 5 and 6, rotation from a first position (see Figs. 3a and 5) is unidirectional toward edge 240 and is

restricted by a radially outward extending stop 247 located circumferentially on the outer surface of rim 230. The collar is permitted to rotate within a recessed region 245 of annular flange 243. In the open position, as shown in Figs. 3a and 5, locking bar 248 on the cap member is opposite complementary locking bar 250 and outward extending stop 247 is positioned along the recessed region 245 proximal to stop bar 250.

To close, the collar locking device is rotated toward locking bar 248 (see Figs. 3b and 6). Additional rotational pressure is required to pass complementary locking bar 250 past locking bar 248 to produce an audible "click". This noise tells the operator that the device is positioned correctly on the Y connector. A recess 248 adjacent to locking bar 250 receives the bar 250 and the outward extending stop 247 moves to a position along recessed region 245 proximal to collar edge 240. In the locked position, diagramed in Figs. 3b and 6, the cut out notch 242 moves beneath archway 204 to provide a locked oval channel or slot to accommodate the arm of the Y connector not actively engaged by the disclosed invention.

As seen in Figs. 3a and 3b, and also in Fig. 4, the rotatable collar 212 is provided with a handle 249 which allows the user of the device to easily grasp the collar 212 for rotation in accordance with the foregoing description. In the embodiment shown, the handle 249 comprises a raised ridge on the collar 212. However, other handles, such as a tab extending from the collar 212, are contemplated within the context of the present invention.

As best seen in Fig. 4, the needle attachment cap 220 is preferably supplied with two or more barbs 252. These engage needle attachment threads 226 in a luer-lock type locking mechanism. The apparatus additionally comprises a needle sheath 254. Thus the safety connector locking device 200 is provided for use as a sterile product that could additionally be provided with or without sterile intravenous drip tubing.

During use, the device 200 is removed from its sterile packaging. Tubing is connected via barbs 222 onto the

intravenous drip attachment tube. Needle 210 is secured to the casing chamber portion of the attachment tube 216 by turning the protective sheath 254 to the right. The needle sheath 254 is removed by pulling outward. The pierceable septum over the Y connector conduit is swabbed with alcohol to decontaminate the puncture site. The cap member is slid over the branch of the Y connector that has been swabbed. Archway 204 is aligned with the crook of the Y connector and the cap member is pushed onto the arm of the Y connector as far as it will go or until the collar locking device can be rotated to form an enclosure around the stalk of the Y connector. Needle 210 should pierce the septum during the connection procedure. The collar 212 is rotated until it locks. In the preferred embodiment, a "click" sound will be heard upon locking due to the locking bar 250 going into the recess 248. Preferably, the drip medication is allowed to flush through the apparatus prior to connecting the intravenous drip to the patient's arm. However this is not always possible, particularly when the intravenous connection is already in place. Thus, the prior flushing step can be omitted.

The addition of the safety connector to the Y connector can be accomplished quickly and precisely without risk of needle puncture or improper insertion in to the arm conduit since the telescopic design guides the cap member to the proper location and the cap member covers the needle tip. The device has minimum removable pieces and is therefore more cost effective to manufacture. It is easy to use and has a low risk for contamination and needle sticks. An audible signal insures that the lock mechanism is in place.

Function of the Cap Member and Port Structure

As will be appreciated from the above description, the cap member 202 provides several functions in a single structure. First, the cap member 202 surrounds the needle 210 and provides a housing in which the needle is lodged safely so that needle sticks are avoided. Second, because the needle is so lodged within the housing, if the nurse did, for example, lay the cap member on the patient's bed, the needle would not

come into direct contact with the bedding which might be infested with harmful bacteria. Thus, this arrangement of the needle deep within the cavity in the cap member 202 provides protection for the patient against bacterial contamination and protection for the nurse against accidental needle sticks.

The port structure also provides more than one function. First, it serves as the site to attach the cap member, and, by means of a simple locking element provides an economical way to modify the conventional piggyback connector so that it may be used with the cap member. Second, the combination of a self-sealing seal and adjacent element that locks the cap member provides a simple way to modify connectors so that they have enhanced safety and convenience.

The cap member 202 and port structure function in combination to direct the needle into the center of the seal, lock these pieces together and enable quick connection. The nurse or patient simply aligns the sealed end of the port structure with the open mouth of the cap member and pushes the two pieces together. The internal wall of the cap member and the exterior wall of the port structure engage to align the two pieces so that their respective axes coincide, guiding the needle into the center of the seal as they are pushed together. Consequently, the needle does not scrape the inside wall of the port structure so that particles of plastic are not introduced into the patient's blood stream and the coring problem is virtually eliminated. The cap member and port structures each carry elements of a locking mechanism which engage and lock the pieces together when the needle has pierced the seal, preventing accidental disconnect. Although other geometric forms may be employed, quick connection is facilitated by the cylindrical configuration of the walls of the cap member and port structure and the circular open mouth of the cavity. In particular, this invention can be very quickly connected because no extra step is required to align the cap member and port structure. All that the nurse need do is insert the port structure into the open mouth without any special concern for their relative positions. Only the extra

step of rotating the two pieces relative to each other is required to engage the locking mechanism.

Because of the features embodied in the cap member and port structure, this invention may be used under normal hospital conditions without creating any additional work for the nurse, while substantially reducing the likelihood of harm to the patient due to carelessness and protecting the nurse against infection and making his or her job easier and faster.

Recapitulation of the Invention

In recapitulation: Our connector is safe because (a) the needle is recessed deeply within the cap member and, therefore, is not likely to be contaminated by bacteria; (b) the cap member and port structure upon engagement guide the needle into the center of the seal, avoiding scraping particles from the inside wall of the port structure; (c) the cap member, housing the needle safely within it, protects the nurse against needle sticks; (d) the locking of the cap member and port structure together prevents accidental disconnects; and (e) the "click" signals the nurse when the connector system is locked securely in position. Our connector is convenient to use because (a) the walls of the cap member and port structure, interacting with each other, provide a guideway for quick connection; (b) the locking mechanism eliminates the burdensome and time consuming task of taping; and (c) the connector is very simple to use so that it is ideal for home care of patients.

Scope of the Invention

The above description presents the best mode contemplated of carrying out the present invention. The combination of features illustrated by these embodiments provide the safety and convenience of this invention. This invention is, however, susceptible to modifications and alternate constructions from the embodiments shown in the drawing and described above. Consequently, it is not the intention to limit it to the particular embodiments disclosed. On the contrary, the intention is to cover all modifications and

alternate constructions falling within the scope of the invention as generally expressed by the following claims.

WHAT IS CLAIMED IS:

1. A safety connector (200) for connection to the branch port on a fluid flow line having a branch port thereon, said connector having a tubular body (202) having proximal and distal ends, and an opening (218) at the distal end of said tubular body (202) for receiving said branch port, said improvements being characterized by:

a radially outwardly extending stop (247) located on the distal end of said tubular body;

a channel (204) in the wall of said tubular body, adjacent the distal end thereof, for receiving said fluid flow line when said branch port is engaged within said tubular body; and

a locking collar (212) having inward and outward facing surfaces rotatably mounted on the distal end of said tubular body, said collar having a slot (236), (240) therein, and said collar (212) rotatable from a first position in which said channel (204) and slot (236), (240) are aligned to receive said fluid flow line when said branch port is engaged within said tubular body (202), and a second position in which said slot (236), (240) in said collar (212) is no longer aligned with said channel (204) and a portion of said collar (212) contacts said branch port a sufficient distance from the intersection of said branch port with said fluid flow line such that said collar (212) prevents removal of said branch port from said tubular body (202), said collar (212) also having a circumferential recessed region (245) in the radially inwardly facing surface of said collar (212), said circumferential recessed region (245) designed to receive said stop (247) on said tubular body (202), whereby the range of rotation of said collar (212) with respect to said body (202) is limited.

2. A safety connector as in Claim 1, wherein said connector (200) is adapted to receive the branch port when said branch port is on a piggyback connector of the type

adapted for combining the fluid flow from two different sources of parenteral fluids.

3. A safety connector as in Claim 2, wherein the two influent lines and the one effluent line of said piggyback connector are arranged in a substantially Y-shaped configuration.

4. A safety connector as in Claim 1, wherein said tubular body (202) is an elongated member having an interior surface and an exterior surface.

5. A safety connector as in Claim 1, further comprising a first luer connection (220), (252) on the interior of said tubular body (202) at the proximal end thereof for receiving the hub of a hollow needle (210) which, when installed, extends distally within said tubular body (202).

6. A safety connector as in Claim 5, further comprising a second luer connector (216), (222) located on the exterior of said tubular body (202) at said proximal end.

7. A safety connector as in Claim 5, wherein said hollow needle (210) is removably disposed in said tubular body (202) and has a proximal attachment end and a sharpened distal end.

8. A safety connector as in Claim 5, wherein the distal end of said hollow needle (210) is disposed within said tubular body (202) at a sufficient distance from the distal end thereof so as to substantially prevent contact between the distal end of said needle and the fingers of an operator handling said safety connector.

9. A safety connector as in Claim 1, wherein said connector (200) is adapted to receive the branch port when said branch port comprises a generally tubular shaped body having a pierceable septum thereon.

10. A safety connector as in Claim 1, wherein said collar (212) has a radially extending, inwardly facing axially oriented ridge (250), wherein a recess formed by another ridge (248) on said tubular body (202) is disposed for receiving said axially oriented ridge (250), said axially oriented ridge

(250) producing an audible click when said collar (212) is rotated into said second position.

11. A safety connector as in Claim 1, wherein said tubular body (202) has a substantially cylindrical surface (234) on the exterior distal end for slidably receiving said collar (212).

12. A safety connector as in Claim 11, wherein said collar (212) has a substantially radially inwardly extending annular flange (243) which slidably mates with an annular shoulder (244) on said cylindrical surface (234) to rotatably secure said collar (212) to said cylindrical surface (234).

13. The safety connector as in Claim 1, wherein said collar (212) has disposed thereon one or more outwardly axially extending ridges (249), whereby a user can readily grasp said collar (212) for rotation.

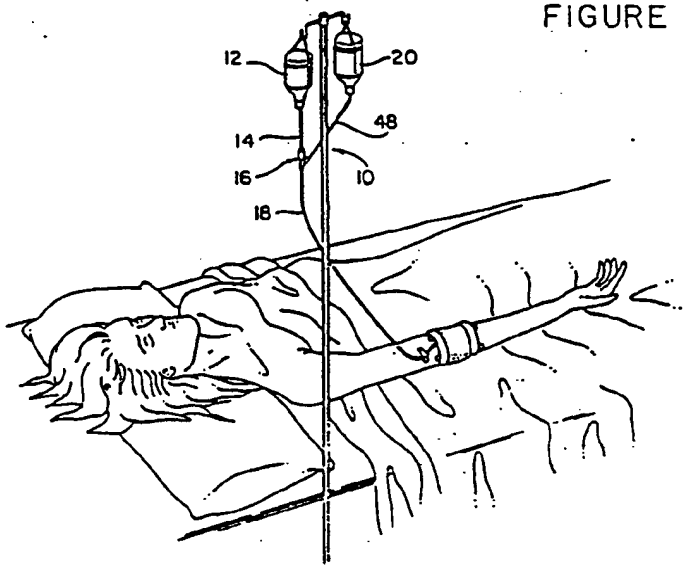
14. A safety connector as in Claim 1, wherein said safety connector (200) is utilized to place an influent fluid line in fluid communication with an effluent fluid line, said effluent fluid line having a pierceable septum thereon.

15. A safety connector as in Claim 14, wherein by causing said branch port to be engaged within said tubular body (202), a needle (210) extending distally within said tubular body (202) pierces said pierceable septum to cause said influent fluid line to be in fluid communication with said effluent fluid line.

16. A safety connector as in Claim 15, wherein by rotating said collar (212) into said second position and preventing the removal of said branch port from said tubular body (202), said collar (212) prevents removal of said needle (210) from said pierceable septum.

17. A safety connector as in Claim 8, wherein said opening (218) is no greater than about one centimeter and said distance between said distal end of said needle (210) and said distal end of said tubular body (202) is greater than about one centimeter.

FIGURE 1



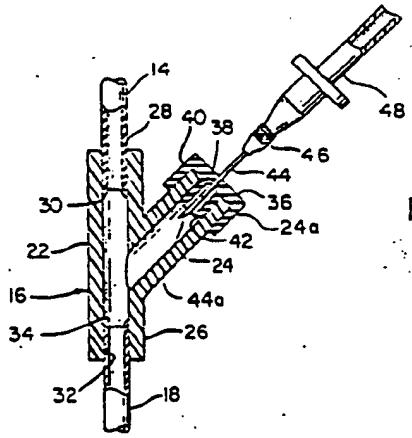
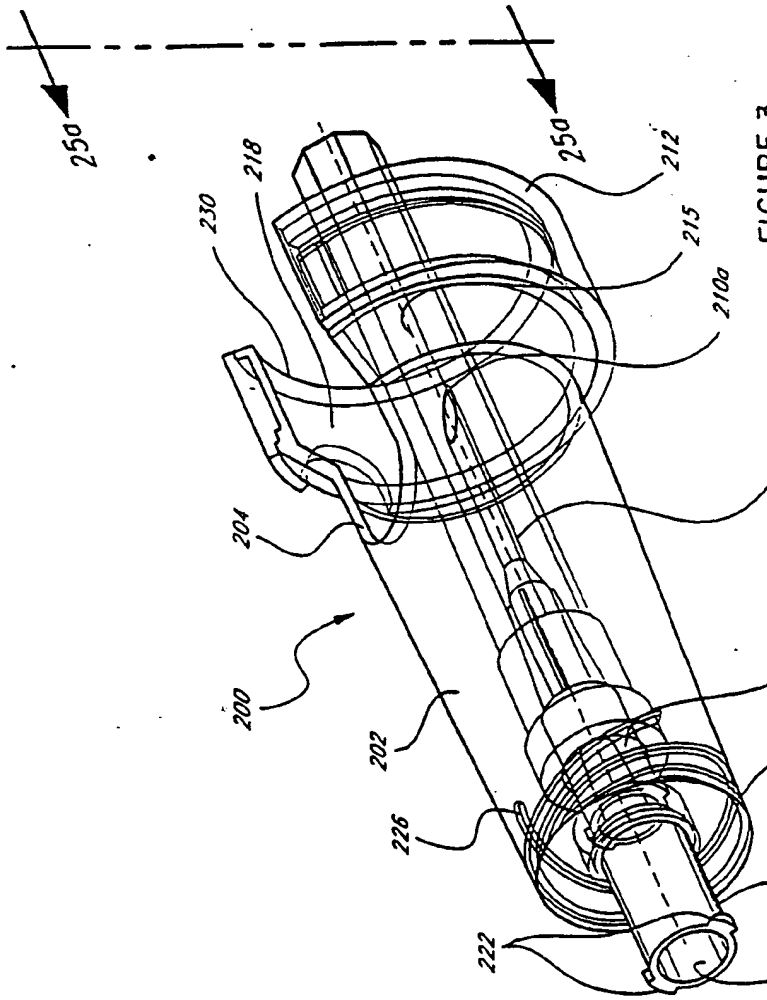


FIGURE 2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250
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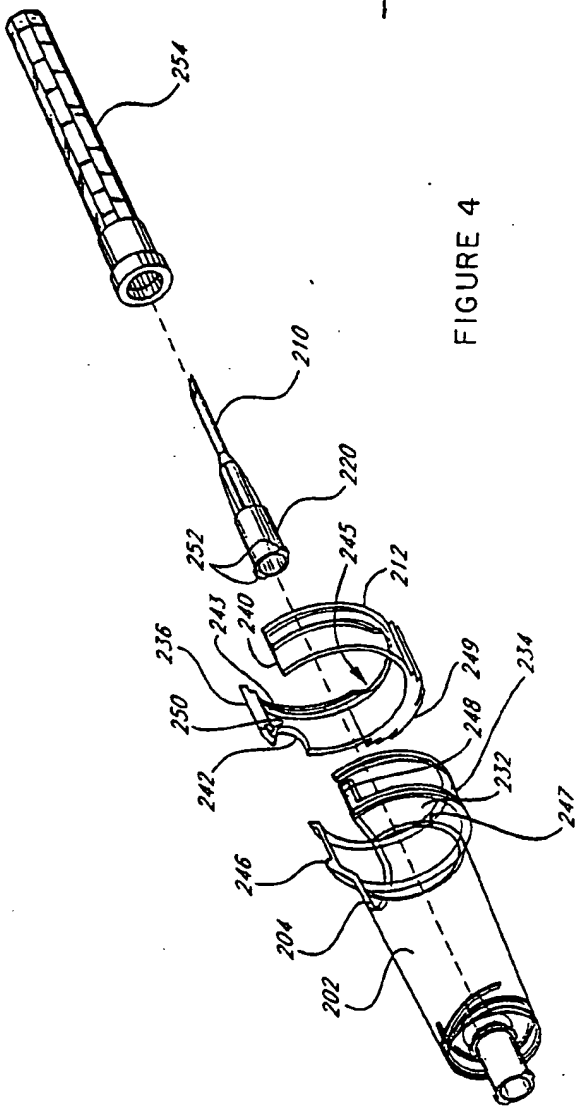
230
215
210a
210
204
220
200
224
202
226
216
222
214

FIGURE 3

3/3


254
210
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245
212
243
240
236
249
234
250
248
242
232
247
246
204
202

FIGURE 4

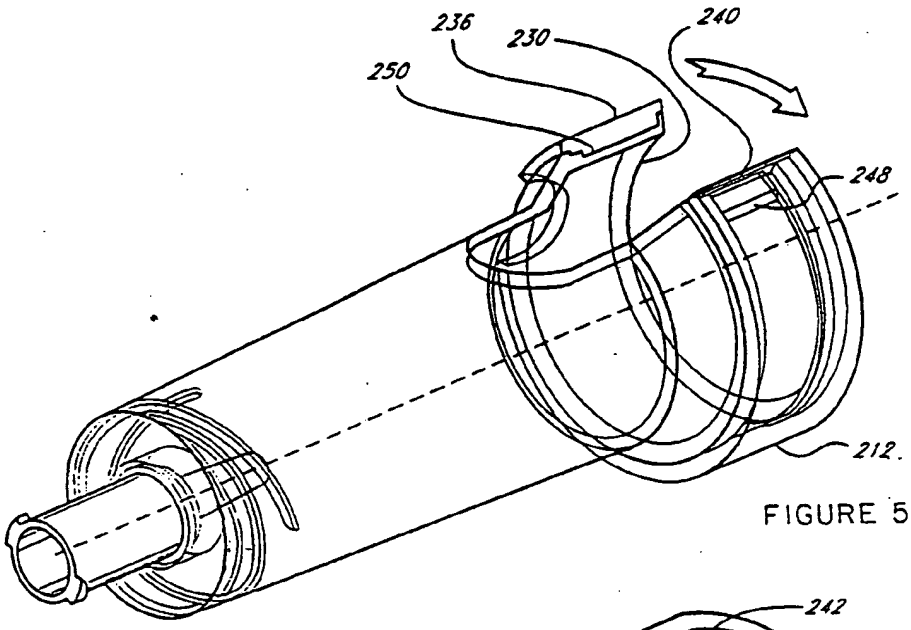

FIGURE 5

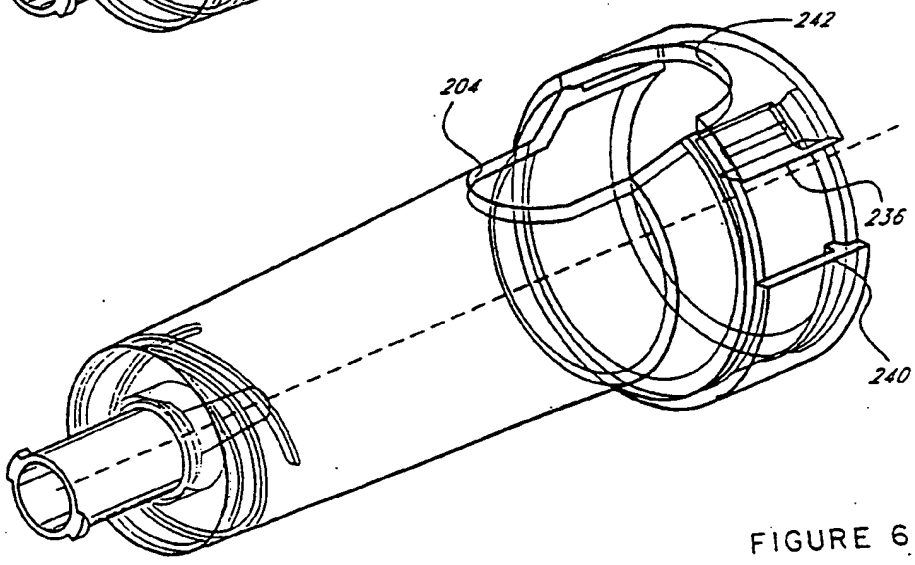

FIGURE 6

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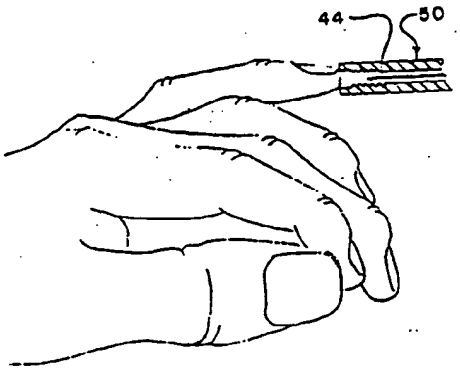

FIGURE 7